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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 18/09/2002
C(2002) 3551

NOT FOR PUBLICATION

COMMISSION DECISION

of 18/09/2002

amending Decision C(2001)286 on the marketing authorization for the medicinal product for human use

"Tenecteplase Boehringer Ingelheim Pharma KG - tenecteplase"

(Text with EEA relevance)

ONLY THE GERMAN TEXT IS AUTHENTIC.

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"Tenecteplase Boehringer Ingelheim Pharma KG - tenecteplase"

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1], as amended by Commission Regulation (EC) No 649/98[2],

Having regard to Commission Regulation (EC) No 542/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) No 2309/93[3], as amended by Commission Regulation (EC) No 1069/98[4], and in particular Article 8(3) thereof,

Having regard to the opinion of the European Agency for the Evaluation of Medicinal Products,

Whereas:

(1) The medicinal product "Tenecteplase Boehringer Ingelheim Pharma KG - tenecteplase" entered in the Community register of medicinal products under Nos EU/1/00/168/001-003 authorised by Commission Decision C(2001)286 of 23 February 2001, as amended, complies with the requirements set out in Regulation (EEC) No 2309/93.

(2) Boehringer Ingelheim International GmbH submitted an application on 22 February 2002 pursuant to Article 6(1) set out in Regulation (EC) No 542/95.

(3) The European Agency for the Evaluation of Medicinal Products delivered a favourable opinion formulated on 30 May 2002 by the Committee for Proprietary Medicinal Products,

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[1] OJ No L 214, 24. 8. 1993, p. 1.
[2] OJ L 88, 24.3.1998, p. 7.
[3] OJ No L 55, 11.3.1995, p. 15
[4] OJ L 153, 27.5.1998, p. 11

(4) Decision C(2001)286 should therefore be amended accordingly.

HAS ADOPTED THIS DECISION:

Article 1

1. The following numbers are added to Article 1 and entered in the Community register of medicinal products.

EU/1/00/168/004	Tenecteplase Boehringer Ingelheim Pharma KG-6,000 units (30 mg)-Powder and solvent for solution for injection -Intravenous use-Powder: vial (glass) Solvent: pre-filled syringe (cycloolefine-copolymen)-6000 units (30 mg)/ml 6 ml (1000 U/ml-5 mg/ml)-1 vial + 1 syringe
EU/1/00/168/005	Tenecteplase Boehringer Ingelheim Pharma KG-8,000 units (40 mg)-Powder and solvent for solution for injection -Intravenous use-Powder: vial (glass) Solvent: pre-filled syringe (cycloolefine-copolymen)-8000 units (40 mg)/ml 8 ml (1000 U/ml-5 mg/ml)-1 vial +1 syringe
EU/1/00/168/006	Tenecteplase Boehringer Ingelheim Pharma KG-10,000 units (50 mg)-Powder and solvent for solution for injection -Intravenous use-Powder: vial (glass) Solvent: pre-filled syringe (cycloolefine-copolymen)-10000 units (50 mg)/ml 10 ml (1000 U/ml-5 mg/ml)-1 vial +1 syringe

2. Annex I is replaced by Annex I to this Decision;

3. Annex III A is replaced by Annex II to this Decision.

Article 2

This Decision is addressed to Boehringer Ingelheim International GmbH, Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland.

Done at Brussels, 18/09/2002

For the Commission
Erkki LIIKANEN
Member of the Commission